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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,855	09/04/2003	Nicolas C. Rivron	1023-271US02	8584

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SHUMAKER & SIEFFERT, P. A.
8425 SEASONS PARKWAY
SUITE 105
ST. PAUL, MN 55125

EXAMINER

PELLEGRINO, BRIAN E

ART UNIT PAPER NUMBER

3738

DATE MAILED: 09/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/656,855

Applicant(s)

RIVRON ET AL.

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/12/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II in the reply filed on 7/8/05 is acknowledged. Claims 1-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Objections

Claim 16 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It is not clear how claim 16 further defines claim 14 because the rubbing of the surface is going to be accomplished in a "luminal direction" since it is done to the luminal surface.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what direction is luminal since Applicant has not

structurally defined the vascular prosthesis. The luminal direction can be in an infinite number of directions.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11,17,19,23,24 are rejected under 35 U.S.C. 102(b) as being anticipated by Bruchman et al. (5879383). Bruchman et al. disclose rubbing a vascular prosthesis (arterial graft) with a tool (swab), col. 18, lines 60-62. Bruchman also discloses mounting the prosthesis on a mandrel, col. 18, lines 56,57. Regarding claims 19,23,24, Bruchman additionally discloses an ePTFE device has a force applied to its surface by passing pressurized water through it, col. 1, lines 23-26.

Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Martakos et al. (5433909). Martakos et al. disclose using PTFE to form a medical device, col. 6, lines 30,31. Martakos also disclose a method of applying a force to a medical device to form the prosthesis, col. 7, lines 9-13,43,44.

Claims 11-13,19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Okuda et al. (EP 790042). Okuda et al. disclose a method of applying a force to an ePTFE medical device by rubbing a tool or rod on the surface as it is inserted in the

tube, page 7, line 24. It is inherent that the rubbing takes place in the transverse direction.

Claims 25-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Dzau et al. (6352555). Fig. 1 shows a vascular prosthesis (2) with a surface (6) including recesses (4). Dzau et al. disclose the device is made of PTFE, col. 5, lines 11-13.

Please note the functional "wherein" clause of the surface including recesses defined by nodes lifted from the surface, carries no weight in the absence of any distinguishing structure. Fig. 2 shows the device has been seeded with cells (14). Dzau et al. also disclose methods of harvesting cells for the prosthesis, col. 5, lines 19-33. Dzau et al. additionally disclose that the cells harvested are endothelial or precursors of endothelial cells, col. 3, lines 13-22. It is inherent that the cells would be seeded less than 15 minutes after harvesting or they would not be viable much longer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-16, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruchman et al. '383. Bruchman et al. is explained supra. Bruchman additionally discloses the vascular prosthesis is everted, col. 18, line 57. However, Bruchman et al. fail to disclose an alternative tool to rub the prosthesis or that the prosthesis is everted

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after rubbing. It would have been an obvious matter of design choice to modify the type of tool used to rub the vessel, since applicant has not disclosed that using the particular brush or brush material provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the "brush" taught by Bruchman or the claimed wheel brush and nylon material in claim(s) 14,15 because both procedures perform the same function of applying a force across the luminal surface of a vascular prosthesis. Regarding claim 16, it is inherent that the rubbing is moving the "brush" across in a luminal direction. It would have been an obvious matter of design choice to modify the sequence of steps, since applicant has not disclosed that using the particular order of everting after rubbing provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the procedure taught by Bruchman or the claimed process of everting the prosthesis after rubbing in claim(s) 18 because both procedures perform the same function of rubbing a luminal surface of a vascular prosthesis.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Okuda et al. (EP 790042). Okuda is explained supra. However, Okuda fails to disclose using a wheel brush with bristles to insert in the ePTFE tube. It is well known in the art that roughened surfaces improve cell adhesion, see WO 96/29030. It would have been an obvious matter of design choice to modify the rod inserted in the ePTFE tube, since applicant has not disclosed that using a wheel brush to modify the surface by rubbing

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provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the procedure taught by Okuda et al. or the claimed wheel brush with bristles in claim(s) 22 because both devices have improved cell adhesion to the vascular prosthesis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Th (7am-4:30pm) and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

Brian E Pellegrino